

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SIGHT SCIENCES, INC.,)	C. A. No.: 21-1317-GBW-SRF
)	
Plaintiff,)	JURY TRIAL DEMANDED
)	
v.)	
)	
IVANTIS, INC., ALCON RESEARCH LLC,)	
ALCON VISION, LLC AND ALCON INC.,)	
)	
Defendants.)	

**LETTER TO THE HONORABLE GREGORY B. WILLIAMS
FROM MELANIE K. SHARP IN SUPPORT OF SIGHT SCIENCES, INC.'S
MOTION TO STRIKE DEFENDANTS' NEW AND UNTIMELY
OBVIOUSNESS-TYPE DOUBLE PATENTING DEFENSE**

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Dear Judge Williams:

None of Defendants' response arguments can overcome Sight's motion to strike. **First**, that Defendants disclosed their ODP defense before the deadline for final invalidity contentions is irrelevant. *E.g.*, Ex. 12 (*ViaTech Techs., Inc. v. Adobe Inc.*, C.A. No. 20-358 ("*ViaTech*") (D. Del. Aug. 1, 2022)) (striking unpled §271(f) theory of infringement from **final** infringement contentions); Ex. 13 (*ViaTech*, D.I. 160) at 24:15-26:11. By adding ODP to their invalidity contentions for the first time after the close of fact and expert discovery, Defendants unilaterally amended their pleadings to inject ODP seven months after the March 2 deadline, without first seeking leave of Court. (D.I. 307 at 1.) Defendants have "shown no good cause for changing the parties' agreed deadline [for amending pleadings] as set in the Court's scheduling order" (*see* D.I. 321 at 1). Defendants should not be permitted to "flagrant[ly] disregard" the Court's scheduling order in this manner. *See Pennypack*, 559 F.2d at 905.

Second, Defendants ignore a key distinction between patent term extension ("PTE") and patent term adjustment ("PTA") articulated by the Federal Circuit in *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1373-74 (Fed. Cir. 2018) ("*Novartis*"). (*See* D.I. 321 at 2-3.) PTE is granted for delays caused by the FDA approval process, whereas PTA compensates for delays caused by the Patent Office. 35 U.S.C. §156; *cf.* §154(b). By statute, a patent subject to a terminal disclaimer **cannot** be awarded PTA (*see* §154(b)(2)(B)), but no analogous restriction exists for PTE. *See* §156. Expressly relying on this distinction, *Novartis* reasoned that "[PTE] is not foreclosed by a terminal disclaimer" and thus not negated by ODP. *Novartis*, 909 F.3d at 1373-74 (citation omitted). Based on this rationale alone, Defendants were on notice in 2018 that ODP can negate PTA. *Id.* Defendants thus misstate the law in asserting that an ODP defense against the '361 and '443 patents was "contrary to the law" before *In re Cellect*. (*See* D.I. 321 at 1; D.I. 307 at 2 (*citing AbbVie and Magna*)). Although the reference to PTA in *AbbVie* is dicta, Defendants should have known from these cases that ODP may be applied to the '361 and '443 patents.^{1,2}

Third, Defendants' "Second Defense (Invalidity)" did not put Sight on notice of any ODP defense. (*See* D.I. 307 at 1.) The two cases cited by Defendants are inapplicable because they were decided at the motion to dismiss stage and did **not** involve an untimely ODP defense. *STC. UNM v. Intel Corp.*, C.A. No. 10-1077 RB/WDS, 2012 U.S. Dist. LEXIS 192494, at *3-5 (D.N.M. May 8, 2012); D.I. 321, Ex. D; *see* Ex. 14 (*Sanofi-Aventis U.S. LLC v. Eli Lilly & Co.*, C.A. 14-113-RGA, D.I. 13 at 1, 4-5, 8-12 (D. Del. Mar. 17, 2014)). Defendants fail to address the Federal Circuit's finding of waiver of an ODP defense disclosed "long after" the deadline to amend pleadings, where invalidity was only pleaded generally. (D.I. 307 (*citing Engineered Prods. Co. v. Donaldson Co.*, 147 F. App'x 979, 986-88 (Fed. Cir. 2005) and *Engineered Prods. Co. v. Donaldson Co.*, 225 F. Supp. 2d 1069, 1082-83, 1123-24 (N.D. Iowa 2022))). Defendants' self-help to an amendment of the pleadings seven months after the deadline should not be countenanced, and even if Defendants had moved to amend, they could not show good cause. *E.g.*, *Cirba Inc. v. VMWare, Inc.*, C.A. No.

¹ The fact that two D.N.J. cases applied *Novartis* to "decline[] to apply ODP to override PTA" (*see* D.I. 321 at 2 (*citing Amgen and Mitsubishi*)) does not alter the fact that other cases have observed that ODP applies to patents with PTA. (D.I. 307 at 2 (*citing AbbVie and Magna*)).

² Defendants assert that Sight's interrogatory 13 is limited to §§ 102 and 103. (D.I. 321 at 1, 3.) But this is due to Defendants' failure to assert ODP as a defense. If Sight had been on notice of any ODP defense, it certainly would have served an interrogatory regarding ODP.

19-742-GBW, 2023 WL 2770686, at *2 (D. Del. Apr. 4, 2023).

Fourth, Defendants’ critique of Sight’s arguments under *Pennypack* fails. Contrary to Defendants’ assertion, ODP is a “question of law with underlying findings of fact.” *E.g., Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1290 (Fed. Cir. 2012) (citation omitted). When undertaking an ODP analysis, the Court must make factual determinations relating to the *Graham* factors, including “(1) the scope and content of the prior art; (2) the level of ordinary skill in the pertinent art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence such as commercial success, long-felt need, and the failure of others.” *Id.* (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)); *Novartis AG v. Ezra Ventures, LLC*, C.A. No. 15-150-LPS, 2016 WL 5334464, at *3 (D. Del. Sept. 22, 2016) (“[T]he Court is not in a position to make [an ODP] determination at the judgment on the pleadings stage of this case” because “[b]oth the ‘same invention’ and ‘obviousness’ inquiries . . . raise **fact issues** (potentially **requiring discovery** and claim construction to resolve)” (emphasis added)); *Studiengesellschaft Kohle mbH v. N. Petrochemical Co.*, 784 F.2d 351, 355 (Fed. Cir. 1986) (refusing to consider ODP defense where proponent offered no evidence of facts relevant to obviousness). Given the underlying factual issues here, Sight would suffer unfair prejudice if the ODP defense is allowed to proceed now. (*E.g., Walker Digital, LLC v. Google Inc.*, C.A. No. 11-309-SLR, 2013 WL 2949109, at *2 (D. Del. June 14, 2013) (granting motion to strike untimely infringement theories that were “not vetted through the discovery process”); *see also* D.I. 307 at 3.) Had Defendants asserted ODP in a timely manner, Sight would have elicited testimony from fact and expert witnesses regarding the differences between the asserted claims of the ’361 and ’443 patents and the claims of the ’328 and ’742 patents. *See UCB, Inc. v. Accord Healthcare, Inc.*, 890 F.3d 1313, 1324 (Fed. Cir. 2018) (ODP requires identifying the differences between the challenged claims and reference claims on a claim by claim basis).³ Having conducted 43 fact and expert depositions, the window has closed to cross-examine Defendants’ witnesses on the relevant factual disputes, and the cost and burden of reopening expert discovery at this late stage would be highly prejudicial to Sight.⁴

Even if exclusion of Defendants’ ODP defense is an “extreme sanction,” it is appropriate here. This Court has routinely excluded evidence under similar circumstances, where a party disregarded a scheduling order and attempted to raise a new defense after fact and expert discovery. *Sysmex Corp. v. Beckman Coulter, Inc.*, C.A. No. 19-1642-GBW, 2022 WL 7008282, at *1-4 (D. Del. Oct. 12, 2022) (striking defenses not disclosed in expert reports or prior invalidity contentions); Ex. 12; Ex. 13 at 24:15-26:11; Ex. 16 (*Galderma Labs., LP v. Amneal Pharms. LLC*, C.A. No. 16-207, D.I. 203 (D. Del. Nov. 29, 2017)) (striking supplemental infringement contentions asserting literal infringement three months after close of fact discovery); D.I. 307, Ex. 11.

³ For example, Sight would have elicited fact testimony and offered expert opinions regarding the differences between claims 58-59 and 70-71 of the ’443 patent, reciting a “kit,” and claims 1, 13, and 17-20 of the ’742 patent, reciting a “method for treating an eye condition.”

⁴ The remaining *Pennypack* factors favor Sight. (D.I. 307 at 2-3.) Only “exclusion of **critical** evidence is an ‘extreme’ sanction.” *Pennypack*, 559 F.2d at 905 (emphasis added) (citation omitted). The ODP defense is not critical in light of Defendants’ other defenses, because it would only apply to about one-third of the asserted claims and striking it “does not leave [Defendants] without an [invalidity] position moving forward.” Ex. 15 (*TQ Delta, LLC v. Comcast Cable Commc’ns LLC*, C.A. No. 15-611-GBW, D.I. 476 at 15 (D. Del. May 24, 2022)).

Respectfully,

/s/ Melanie K. Sharp

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MKS:mg

cc: All Counsel of Record (via CM/ECF and e-mail)
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